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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/757,781	01/09/2001	Roopa Reddy	PC-0032 US	8475

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EXAMINER

RAWLINGS, STEPHEN L

ART UNIT PAPER NUMBER

1642

DATE MAILED: 07/02/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/757,781

Applicant(s)

REDDY ET AL.

Examiner

Stephen L. Rawlings, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 February 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 2 and 9-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other:  |

### DETAILED ACTION

1. The amendment filed February 24, 2003 in Paper No. 12 is acknowledged and has been entered. Claims 1, 3, and 4 have been amended.
2. Claims 1-22 are pending in the application. Claims 2 and 9-22 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim. Applicants timely traversed the restriction (election) requirement in Paper Nos. 8 and 10.
3. Claims 1 and 3-8 are currently under prosecution.

#### ***Grounds of Objection and Rejection Withdrawn***

4. Unless specifically reiterated below, the grounds of objection and rejection set forth in the previous Office action mailed December 3, 2002 (Paper No. 11) are withdrawn.

Nevertheless, for clarity of record the following comments are made:

Claims 1 and 3-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed. However, part of the grounds of this rejection has been withdrawn. Specifically, although the term "cDNA encoding a protein" is ambiguously defined on page 7 as "a nucleic acid that closely aligns with sequences that encode conserved regions, motifs or domains that are identified by employing analyses well known in the art" (specification, page 7, lines 4-6), a definition that might reasonably encompass a genomic DNA isolate, in Paper No. 12, Applicants have stated, "a cDNA is always derived from messenger RNA (mRNA) that is itself derived entirely from exons of genomic DNA and cannot contain introns of genomic DNA" (underlining in original; Paper No. 12, page 7, paragraph 6). Therefore, claims 1 and 3, which are specifically drawn to an isolated "cDNA, or the complement thereof, encoding a protein" are here

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forth limited to a complementary DNA (cDNA) molecule that is derived from an mRNA molecule so that the claims do not encompass genomic DNA isolates. Accordingly, as the claims are no longer interpreted as claims to "genes encoding a polypeptide", this part of the grounds of rejection of the claims under 35 USC § 112, first paragraph has been withdrawn.

Claims 1, 3, and 5-8 were rejected under 35 USC §112, second paragraph, as being vague and indefinite because claims 1 and 3 recite the term "isolated cDNA [...] encoding a protein". As stated in the Office action mailed December 3, 2002 (Paper No. 11), recitation of the term "cDNA [...] encoding a protein" renders the claims vague and indefinite because on page 7 the specification defines the term as "a nucleic acid sequence that closely aligns with sequences which encode conserved regions, motifs or domains that were identified by employing analyses well known in the art". Therefore, it is unclear how closely the claim requires the claimed nucleic acid sequence to align with sequences that encode conserved regions, motifs, or domains of a protein having the amino acid sequence set forth in SEQ ID NO: 2 or a naturally occurring variant thereof. Additionally, it is unclear to which conserved regions, motifs, or domains of the amino acid sequence of SEQ ID NO: 2, an antigenic epitope thereof, a biologically active portion thereof, or variant of SEQ ID NO: 2 the claims require the claimed nucleic acid sequence to closely align. Finally, it is unclear which analyses, which are well known in the art, were used to identify said conserved regions, motifs, or domains. Nevertheless, as noted in the paragraph above, Applicants have stated, "a cDNA is always derived from messenger RNA (mRNA) that is itself derived entirely from exons of genomic DNA and cannot contain introns of genomic DNA" (underlining in original; Paper No. 12, page 7, paragraph 6). As such, claims 1 and 3, which are specifically drawn to an isolated "cDNA, or the complement thereof, encoding a protein" are here forth limited to a complementary DNA (cDNA) molecule that is derived from an mRNA molecule encoding the protein, so that in view of Applicants' remarks, the claims are no longer regarded as indefinite or vague.

Claim 8 was rejected under 35 USC §112, second paragraph, as being indefinite because the claim recites, "using a cDNA to produce a protein". As stated in the Office

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action mailed December 3, 2002 (Paper No. 11), the claim does not clearly delineate the metes and bounds of the invention, as it cannot be determined whether the protein to which the phrase refers is the protein encoded by the cDNA molecule of claim 1 or any cDNA molecule of which the cell is comprised. In Paper No. 12, Applicants have stated, "the method of claim 8 can only be used to produce a protein described in claim 1" (Paper No. 12, page 14, paragraph 4). In view of Applicants' statement, this ground of rejection under 35 USC § 112, second paragraph has been withdrawn.

Claims 4 is rejected under 35 U.S.C. 102(b) as being anticipated by NCI-CGAP (Database GenBank Accession No. AI079538, 1998). However, part of the grounds of this rejection has been withdrawn. The nucleic acid molecule of the prior art comprises SEQ ID NO: 21, but does not anticipate the claimed invention, because the nucleic acid molecule of the prior art does not comprise a sequence that is a fragment of SEQ ID NO: 20 consisting of SEQ ID NO: 21. Moreover, the nucleic acid molecule of the prior art comprises a sequence that is a fragment of SEQ ID NO: 20, but which does not consist of SEQ ID NO: 21.

It is believed that all other reasons for the withdrawal of any other grounds of objection and rejection should be apparent.

#### ***Response to Applicants' Remarks***

5. In Paper No. 12, Applicants have remarked that recitation of inactive hyperlinks, or other references to particular websites on the Internet, should be permitted.

In reply to Applicants' remarks, MPEP 608.01(p) does not provide for incorporation of essential or non-essential material by reference to hyperlinks or other forms of browser-executable code. Essential subject matter may only be incorporated by reference to (1) US patents and pending US applications, or patents or other publications published by a foreign country or a regional patent office, (2) non-patent publications, (3) a US patent or application which itself incorporates material by reference, or (4) a foreign application. Non-essential information may be incorporated by reference to (1) patents or applications published by the United States, or patents or

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other publications published by a foreign country or a regional patent office, (2) prior filed, commonly owned US applications, (3) non-patent publications.

It is impermissible that a patent's disclosure incorporate essential or non-essential material by reference to embedded hyperlinks and/or other forms of browser-executable code, because the information contained in the websites or databases to which the hyperlinks or other forms of browser-executable code connect may not be maintained on the Internet for the duration of the patent's term and may not contain the same information after the filing date of an application that was contained in the website or database on or before the filing date of the application. Since the information contained in a website may vary, it is not evident that information contained in a website will always remain useful the practitioner or even applicable to the invention; and information contained in an extinct website cannot possibly be helpful to the practitioner. Furthermore, the validity of a patent containing a reference to a hyperlink or other form of browser-executable code may be reasonably questioned if the website(s) to which the hyperlink(s) connect were relied upon by the patentee(s) to provide sufficient disclosure or description of the invention to meet the requirements of 35 USC § 112, first and second paragraphs.

A hyperlink or other form of browser-executable code may be permitted if the hyperlink or other form of browser-executable code is part of the claimed invention, but in this case, the Office would disable the hyperlink or other form of browser-executable code.

In general, if the Applicant expects to rely upon the information contained in the websites or databases to provide antecedent basis for the subject matter of claims in a parent application or related applications, and if the material is properly incorporated by reference in the referencing application, Applicant would be required to amend the specification of the referencing application to include the material incorporated by reference to the hyperlink or other forms of browser-executable web, or other non-permissible sources and to provide a declaration by Applicant or Applicant's representative stating that the amendatory material consists of the same material incorporated by reference in this application. See MPEP § 608.01(p).

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In the instant application, the specification referred to hyperlinks that connect to widely used, publicly available databases. Applicant is reminded that it is not necessary to disclose that which is widely known in the art.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1 and 3-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for part of the reasons set forth in the Office action mailed December 3, 2002 (Paper No. 11).

Claim 1 is specifically drawn to a cDNA encoding "a naturally occurring variant" of the polypeptide of SEQ ID NO: 2; and claim 3 is specifically drawn to a cDNA comprising a sequence of "a naturally occurring variant" of SEQ ID NO: 20.

The specification does not describe a description of the structure of a nucleic acid molecule encoding a variant of the polypeptide of SEQ ID NO: 2 having an amino acid sequence that is at least 95% identical to SEQ ID NO: 2; nor does the specification describe a cDNA molecule comprising the polynucleotide sequence of a naturally occurring variant of a cDNA comprising the polynucleotide sequence of SEQ ID NO: 20 having at least 90% identity to SEQ ID NO: 20. As such, the description of the claimed invention would not be sufficient to reasonably convey to the skilled artisan that Applicants had possession of the claimed invention at the time the application was filed.

Applicants have traversed this ground of rejection in Paper No. 12, arguing that the specification describes specific features common to AISP-related proteins, such as conserved PDZ domains and the aPCK binding region. Applicant has contended that the specification describes variants of SEQ ID NO: 2 at, for example, page 3, lines 6

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and 7, which Applicants has further contended is an adequate description of the claimed invention. Finally, Applicants have argued that the claimed genus of cDNA molecules is of narrow scope, or not highly variant, and point to the disclosure of Brenner et al. as evidence of this assertion.

Applicants' argument have been carefully considered but not found persuasive for the following reasons:

MPEP § 2163.02 states, "[a]n objective standard for determining compliance with the written description requirement is, 'does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed' ". The courts have decided:

The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the "written description" inquiry, *whatever is now claimed*.

See *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Federal Circuit, 1991). Furthermore, the written description provision of 35 USC § 112 is severable from its enablement provision; and adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

*The Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, paragraph 1, "Written Description" Requirement* (66 FR 1099-1111, January 5, 2001) state, "[p]ossession may be shown in a variety of ways including description of an actual reduction to practice, or by showing the invention was 'ready for patenting' such as by disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention" (*Id.* at 1104). Moreover, because the claims encompass a genus of variant species, an adequate written description of the claimed invention must include sufficient description of at least a representative number of species by actual reduction to practice, reduction to drawings,



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or by disclosure of relevant, identifying characteristics sufficient to show that Applicants were in possession of the claimed genus. However, factual evidence of an actual reduction to practice has not been disclosed by Applicants in the specification; nor have Applicants shown the invention was "ready for patenting" by disclosure of drawings or structural chemical formulas that show that the invention was complete; nor have Applicants described distinguishing identifying characteristics sufficient to show that Applicants were in possession of the claimed invention at the time the application was filed.

Applicants have argued that Brenner et al. provides evidence that the members of the claimed genus of cDNA molecules are not highly variable, so that the description that the members of the claimed genus encode polypeptides that are at least 95% identical to SEQ ID NO: 2 should be regarded as sufficient to describe the invention as required under 35 USC § 112, first paragraph. According to Applicants' argument: "Through exhaustive analysis of a data set of proteins with known structural and functional relationships and with >90% overall sequence identity, Brenner et al. have determined that 30% identity is a reliable threshold for establishing evolutionary homology between two sequences aligned over at least 150 residues" (Paper No. 12, page 11, paragraph 3). In reply, establishing that two polypeptides are evolutionarily related would not establish that a polypeptide, which is at least 95% identical to another but nonetheless different, will bear the same structure or function as the other; and Brenner et al. does not appear to teach otherwise.

In further reply to Applicants' apparent argument that 30% identity is a reliable threshold for establishing functional correlations between structurally similar proteins, Skolnick et al. (*Trends in Biotechnology* **18**: 34-39, 2000) disclose that the skilled artisan is well aware that assigning functional activities for any particular protein or protein family based upon sequence homology is inaccurate, in part because of the multifunctional nature of proteins (see, e.g., the abstract; and page 34, *Sequence-based approaches to function prediction*). Even in situations where there is some confidence of a similar overall structure between two proteins, only experimental research can confirm the artisan's best guess as to the function of the structurally related protein (see,

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in particular, the abstract and Box 2). Thus, one skilled in the art would not accept the assertion, which is based only upon an observed similarity in amino acid sequence, that a variant of the polypeptide of SEQ ID NO: 2 would be found to be functionally identical to the polypeptide of SEQ ID NO: 2. Therefore, as evidenced by the teachings of Skolnick et al., the art is unpredictable.

In addition, contrary to Applicants' assertions, the disclosure of Brenner et al. does not appear to support the argument that the members of the claimed genus of cDNA molecules are not highly variable. The *Guidelines* state, "[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species *cannot* be achieved by disclosing only one species within the genus" (Id. at 1106); accordingly, it follows that an adequate written description of a genus cannot be achieved in the absence of a disclosure of at least one species within the genus.

8. Claims 1 and 4-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reason set forth in the Office action mailed December 3, 2002 (Paper No. 11).

Claims 1 and 4 recite the terms "a naturally occurring variant of [...] SEQ ID NO:2" and "a naturally occurring variant of [...] SEQ ID NO:20", respectively. However, there does not appear to be proper and sufficient antecedent basis in the specification for recitation of these terms in the claims. Therefore, recitation of the terms in the claims appears to introduce new matter and thereby violates the written description requirement set under 35 USC § 112, first paragraph.

Applicants have traversed this ground of rejection arguing that proper and sufficient antecedent basis for the recitation of the limitation "naturally occurring" can be found in the specification at pages 7, 12, and 13.

Applicants' arguments have been carefully considered but not found persuasive because the disclosure to which Applicants have pointed do not provide proper and sufficient antecedent basis for limiting the claimed cDNA molecules to those that are a

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"naturally occurring variant" of the nucleic acid molecule of SEQ ID NO: 20, or which encode a "naturally occurring variant" of the polypeptide of SEQ ID NO: 2. The disclosure at page 7, refers to derivatives of naturally occurring molecules, but does not provide explicit or implicit support for the recitation of the limitation "naturally occurring variant" in the claims. The disclosure at page 12 states, "as a result of the degeneracy of the genetic code, a multitude of cDNA encoding ARP, some bearing minimal similarity to the cDNAs of any known and naturally occurring gene, may be produced" (lines 39-41); thus, this disclosure also does not provide the necessary antecedent basis. Finally, the disclosure at page 13 refers to possible variations in the structure of a cDNA molecule encoding a polypeptide, which could be *made* by selecting combinations based on possible codon choices in accordance with the standard triplet genetic code as applied to the polynucleotide encoding naturally occurring ARP. Accordingly, the disclosure at page 13 does not provide antecedence for the recitation of the limitation of "naturally occurring variant" in the claims.

9. Claims 3 and 4 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

(a) Claim 3 recites the limitation, "from about amino acid residue K189 to about amino acid residue Q236 of SEQ ID NO:2". However, there does not appear to be a proper and sufficient antecedent basis in the specification to support the recitation of this limitation in the claim. Therefore, the recitation of the limitation in the claim appears to introduce new matter, thereby violating the written description requirement set forth under 35 USC § 112, first paragraph.

(b) Claim 4 recites the limitation, "comprising" in line 1. There does not appear to be a proper and sufficient antecedent basis in the specification to support the recitation of this limitation in the claim, since the originally claim 1 was drawn to an isolated cDNA, which is selected from (a) a nucleic acid of SEQ ID NO: 20, or its complement, (b) a fragment of SEQ ID NO: 20, which is SEQ ID NO: 21, and (c) a

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naturally occurring variant of SEQ ID NO: 20. Therefore, the recitation of the limitation "comprising" in the claim appears to broaden the scope of the claimed invention and thereby introduce new matter in violation of the written description requirement set forth under 35 USC § 112, first paragraph.

These issues might be resolved if Applicants were to point to specific disclosures in the specification, as originally filed, which Applicants believe provide the necessary explicit or implicit support for the recitation of the limitations in the claims.

### ***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claim 4 is rejected under 35 U.S.C. 102(a) as being anticipated by Joberty et al. (*Nature Cell Biology* 2: 531-539, 2000) for the part of the reasons set forth in the Office action mailed December 3, 2002 (Paper No. 11).

Joberty et al. teach a nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 20.

Applicants have traversed this ground of rejection arguing that "the Joberty sequence differs significantly from that of applicants sequence and therefore [...] the nucleic acid molecule of Joberty et al. does not anticipate, and therefore cannot "comprise" the nucleic acid sequence of SEQ ID NO:20" (Paper No. 12, paragraph bridging pages 14 and 15).

Applicants' arguments have been carefully considered but not found persuasive. Claim 4 is drawn to a cDNA comprising a sequence of a nucleic acid sequence of SEQ ID NO: 20, or its complement. The nucleic acid molecule of the prior art has a

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polynucleotide sequence that comprises a sequence of the polynucleotide sequence set forth in SEQ ID NO: 20. The specification teaches, "the singular forms 'a', 'an', and 'the' include plural reference unless the context clearly dictates otherwise" (specification, page 6, lines 12 and 13). Thus, consistent with the example set forth at page 6, in lines 13 and 14, "a sequence", as recited in claim 4, is read as a plurality of sequences, or a plurality of two or more contiguous nucleotides of SEQ ID NO: 20. Because the nucleic acid molecule of the prior art comprises one or more sequences of the polynucleotide sequence set forth in SEQ ID NO: 20, the disclosure of the prior art is deemed anticipatory of the claimed invention.

12. Claim 4 is rejected under 35 U.S.C. 102(b) as being anticipated by Izumi et al. (*Journal of Cell Biology* **143**: 95-106, 1998).

Izumi et al. teach a nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 20.

Applicants have traversed this ground of rejection arguing that the prior art does not anticipate the claimed invention because the nucleic acid molecule of the prior art does not comprise the polynucleotide sequence of SEQ ID NO: 20.

Applicants' arguments have been carefully considered but not found persuasive for the same reasons that Applicants' traversal of the rejection of claim 4, as being anticipated by Joberty et al., was not persuasive.

13. Claims 4 is rejected under 35 U.S.C. 102(b) as being anticipated by NCI-CGAP (Database GenBank Accession No. AI079538, 1998).

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The nucleic acid molecule of the prior art comprises a nucleic acid sequence of SEQ ID NO: 20; in fact, the nucleic acid molecule comprises SEQ ID NO: 21.

Applicants have traversed this ground of rejection arguing that the prior art does not anticipate the claimed invention because the nucleic acid molecule of the prior art does not comprise the polynucleotide sequence of SEQ ID NO: 20.

Applicants' arguments have been carefully considered but not found persuasive for the same reasons that Applicants' traversal of the rejection of claim 4, as being anticipated by Joberty et al., was not persuasive.

### ***Conclusion***

14. No claims are allowed.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (703) 305-3008. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Stephen L. Rawlings, Ph.D.  
Examiner  
Art Unit 1642

slr  
June 17, 2003

  
ANTHONY C. CAPUTA  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600